

Message Text

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ACTION OES-06

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FM AMEMBASSY TOKYO

TO SECSTATE WASHDC 3910

UNCLAS TOKYO 17673

FOR OES/APT/BMP; EB

DEPT PASS DHEW/OIH; FDA

E.O. 11652: N/A

TAGS: TBIO, JA

SUBJECT: RELAXATION OF MINISTRY OF HEALTH AND WELFARE RESTRICTIONS
ON PRE-CLINICAL TESTING OF NEW DRUGS

REF: TOKYO 17493, TOKYO A-395

1. FOLLOWING DISPATCH REFTEL, EMBASSY HAS RECEIVED FURTHER INFO
RE PROCEDURE FOR SUBMISSION OF TEST DATA OBTAINED IN FOREIGN
LABORATORIES. IN ORDER TO SATISFY REQUIREMENTS OUTLINED IN
RECENTLY ISSUED MHW NOTICE (POUCHED TO OES), FOREIGN COMPANIES
WILL HAVE TO PROVIDE THE FOLLOWING, AMONG OTHER THINGS:

A) A DESCRIPTION OF THE LABORATORY PERSONNEL WITH AN ORGANIZATION
CHART. THE PRINCIPAL INVESTIGATOR(S) MUST BE IDENTIFIED AND
PERSONAL HISTORY COVERING HIS ACADEMIC AND PROFESSIONAL CAREERS
MUST BE SUPPLIED. ANY AWARDS HE HAS WON SHOULD BE LISTED. A
BIBLIOGRAPHY OF RESEARCH PAPERS PUBLISHED BY THE PRINCIPAL RESEARCHER
(S)
MUST BE SUBMITTED TOGETHER WITH THE NAMES OF ANY SCIENTIFIC SOCIETIES
HE BELONGS TO AND PERIODS OF MEMBERSHIP THEREIN.

B) TRANSLATIONS SHOULD BE MADE USING COLLOQUIAL JAPANESE. A
TRANSLATOR EXPERIENCED IN WORKING WITH THE TERMINOLOGY
OF THE PHARMACEUTICAL INDUSTRY IS NECESSARY TO DO THIS WORK;
THIS MAY PRECLUDE USE OF THE MAJORITY OF JAPANESE TRANSLATORS
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IN THE U.S.

C) THE REQUIRED APPROVAL OF USE FROM A FOREIGN GOVERNMENT WHICH MUST BE SUBMITTED NEED NOT BE FROM THE GOVERNMENT OF THE COUNTRY WHERE THE DRUG WAS FIRST INVENTED BUT ANY AND ALL ACUTE AND SUBACUTE TOXICITY TEST DATA NO MATTER WHERE DONE MUST BE SUBMITTED IN ADDITION TO THE DATA FROM THE TESTS DONE IN JAPAN.

D) ONE GUIDELINE STIPULATES THAT THE APPLICANT IS EXPECTED TO MAINTAIN THE TEST DATA AND SPECIMENS FOR FIVE YEARS FOLLOWING THE DATE OF APPROVAL FOR IMPORT OF THE PRODUCT. IF THE APPLICANT HAS A CONTRACT WITH THE LABORATORY WHICH CONDUCTED THE ORIGINAL TESTS TO MAINTAIN THE DATA AND SPECIMENS, A COPY OF THE CONTRACT MUST BE SUPPLIED WITH THE APPLICATION.

2. ALL OF THE REQUIREMENTS LISTED ABOVE ARE CONSIDERED QTE ADMINISTRATIVE GUIDANCE UNQTE. THEY DO NOT APPEAR IN THE OFFICIAL LIST OF GUIDELINES BUT THEY WILL HAVE AN IMPORTANT EFFECT ON THE UTILITY OF NEW RULES TO U.S. (AND OTHER) COMPANIES.

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